

at 30-31, bridging paragraph.) The specification teaches that the invention concerns all extracts of the virus, including crude lysates, more purified lysates, and purified proteins. (*Id.* at 14, paragraph 3.) The specification teaches detailed purification procedures for the generation of crude viral extracts, and detailed procedures for the generation of purified viral antigens, which include p12, p18, p25, p15, p36, p42, and p80. (*Id.* at 11-13 and 21-23.)

The specification teaches that the invention concerns proteins or polypeptides (purified or not) as such, free of the extract. (*Id.* at 14, lines 20-21.) The specification teaches the HIV-1 p25, p18, and p12-p13 proteins, and extracts containing these proteins. (*Id.* at 14-15.) The skilled artisan is taught that the invention relates to the use of viral extracts (both crude lysates and purified proteins) to generate antibodies in animals, as well as to generate monoclonal antibodies. (*Id.* at 30-31, bridging paragraph.)

The specification teaches using HIV-1 proteins as immunogens for the production of antibodies for detection of proteins associated with the retrovirus:

Methods and compositions are provided for detecting the presence of a retrovirus associated with lymphadenopathy syndrome and/or acquired immune deficiency syndrome. The compositions may be derived, either directly or indirectly from the retrovirus. **The proteins may be used as reagents for detection of the presence of antibodies in human blood as indicative of a prior or existent infection with the retrovirus, as immunogens for the production of antibodies for detection of proteins associated with the retrovirus, or as vaccines.** The absence of a reaction is indicative of a negative diagnosis.

(Specification at 4, lines 1-10.) There can be no doubt that applicants contemplated making and using the claimed antibodies. Accordingly, applicants respectfully request withdrawal of the rejection.

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The specification describes the purification of immunocomplexes formed by interaction of patient sera with viral extracts. (*Id.* at 12, paragraph 2.) Applicants further submit that immunoprecipitation is an art recognized technique for purifying immune complexes. As detailed above, the specification teaches purified p12, p18, p25, p15, p36, p42, and p80 HIV-1 antigens. The skilled artisan is taught that immune complexes between these antigens and anti-HIV-1 antibodies can be purified by immunoprecipitation. (*Id.*) Furthermore, the specification teaches that the invention encompasses any type of immunological assay, and recites immunofluorescence, immunoenzymatic assays, and radioimmunoprecipitation assays as particularly suitable. (*Id.* at 14, paragraph 2.) As an additional example, the specification teaches detailed procedures for purifying immunocomplexes between HIV-1 extracts and anti-HIV-1 antibodies using an ELISA. (*Id.* at 17-26.) The specification also teaches labeled virus extracts including fluorescent, enzymatic, and radioactive labeling. (*Id.* at 17, paragraph 5.) As an example, the specification teaches using an enzymatically labeled antibody. (*Id.* at 17-18.)

Applicants detected antibodies to p12, p13, p19, p42, and p80 proteins in the sera of lymphadenopathy and AIDS patients with compositions containing one or more of the proteins. (Specification at 15, lines 23-25.) There can be no doubt that applicants contemplated making and using the claimed immune complexes. Accordingly, applicants respectfully request withdrawal of the rejection.

Claims 18-20 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6, 10-13, and 18-22 of U.S. Patent No.

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5,135,864. Claims 18-20 are no longer pending in this application. Accordingly, applicants submit that the rejection is in error.

Claims 37-44 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 5, 7, and 9-11 of U.S. Patent No. 5,217,861. The Examiner asserts that it would have been *prima facie* obvious to generate antibodies against the p12, p18, and p25 antigens disclosed in the '861 patent.

Applicants traverse the rejection. As outlined in M.P.E.P. § 804, a obviousness-type double patenting rejection is primarily intended to prevent the prolongation of the patent term by prohibiting claims in a second patent that are not patentably distinct from claims in a first patent. Applicants submit that the antibodies and immune complexes of the claims in the instant application are patentably distinct from the antigens of the '861 patents. It is art recognized that antibodies and antigens are distinct subject matter. Accordingly, applicants respectfully request withdrawal of the rejection.

Applicants respectfully submit that this application is now in condition for allowance. In the event that the Examiner disagrees, he is invited to call the undersigned to discuss any outstanding issues remaining in this application in order to expedite prosecution.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: April 10, 2002

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